Kisunla

India · access guide

Kisunla access in India: the CDSCO named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Patients in India access Kisunla (donanemab-azbt) for early symptomatic Alzheimer's disease with amyloid-confirmed pathology through the CDSCO Rule 36 personal-import authorisation, a federal mechanism that allows a treating Indian physician to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in INR.

Why India patients need Kisunla through the named-patient pathway

India's pharmaceutical regulatory landscape is administered by the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare. The Drugs and Cosmetics Act 1940 and the New Drugs and Clinical Trials Rules 2019 establish the framework for marketing authorisation, personal-use import, and patient-specific access. Despite India's status as a global generics manufacturer, originator specialty biologics, CAR-T cell therapies, and newer monoclonal antibodies frequently reach Indian patients through cross-border named-patient routes before local launch or after local stockouts. Until the 2023-2024 anti-amyloid antibody approvals, Alzheimer's disease had no disease-modifying therapy. Leqembi (lecanemab) received traditional FDA approval in July 2023 with biweekly IV dosing and a target on soluble protofibrils and insoluble fibrils. Kisunla (donanemab) received traditional FDA approval in July 2024 with monthly IV dosing, a target on deposited plaque, and the distinguishing feature of label-permitted discontinuation once amyloid plaque clearance is confirmed. The two products together establish the anti-amyloid antibody class as the first disease-modifying option for early Alzheimer's disease and are reshaping the standard of care alongside symptomatic agents (cholinesterase inhibitors and memantine).

For Kisunla specifically, three converging patterns drive India cases. First, indication or product lag. Originator specialty medicines like Kisunla (donanemab-azbt) reach local registration in India months to years after FDA approval, and in many cases the FDA-labelled indication, the specific product configuration, or the manufacturing slot for the patient is not locally available. Second, payer or formulary constraint. Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Max Bupa (Niva Bupa), and corporate group policies each assess high-cost specialty therapies case by case, and a patient who clinically fits the FDA label can still face an uncovered claim or a step-therapy denial that consumes weeks the disease will not wait through. Third, brand-specific clinical reasoning. The treating neurologist or memory-disorders specialist may have made a deliberate decision based on the patient's phenotype, prior-therapy exposure, or comorbidity profile, and substituting a different molecule simply because it is what the local pharmacy stocks is not the right clinical call.

In each pattern, the named-patient pathway is the legal mechanism that connects a India-licensed physician's clinical decision with US-sourced, FDA-labeled product for a specific identified patient. It is not a workaround; it is the framework the regulator has established for precisely these gaps.

The CDSCO named-patient pathway for Kisunla

The Indian framework for patient-specific import of an unregistered medicine is the personal-use import permission under Rule 36 of the New Drugs and Clinical Trials Rules 2019, combined with the personal-import exemption under the Drugs and Cosmetics Rules. CDSCO grants permission for a treating physician at a registered hospital to import a specific medicine for a specific named patient when the medicine is approved by a stringent regulatory authority (US FDA, EMA, MHRA, PMDA, Health Canada, or TGA) and no clinically equivalent registered alternative is suitable. Applications route through the CDSCO SUGAM portal (cdscoonline.gov.in). For Kisunla specifically, the clinical justification typically frames the case around the precise FDA-approved indication and the documented gap in the local route.

A complete application includes a clinical justification letter from the treating physician (diagnosis, severity, prior therapies, why this specific drug, why the locally stocked option is not suitable for this case), the treating physician's license verification through the State Medical Council of the practising state and the Medical Council of India / National Medical Commission, an anonymised patient identifier where the CDSCO submission allows, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity requested, intended treatment duration), the destination dispensing facility name, license number, and pharmacy or cell-therapy laboratory in charge, and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing facility, including cold-chain or cryogenic handling specific to the product format.

Kisunla is indicated for the treatment of Alzheimer's disease in adults with mild cognitive impairment (MCI) or mild dementia stage, with confirmed amyloid pathology by amyloid PET imaging or cerebrospinal fluid (CSF) biomarkers. The drug is not indicated for moderate or severe Alzheimer's, for non-Alzheimer's dementia, or for patients without amyloid biomarker confirmation. The clinical justification for Kisunla typically documents the specific indication criterion that the patient meets, the prior-therapy history that establishes label eligibility, and the operational plan at the treating hospital.

CDSCO routine processing for Rule 36 personal-import applications is typically 15 to 30 business days from complete submission. Complex cases (CAR-T, first-of-kind biologics, gene therapy) can extend to 8 to 12 weeks. State drug controller endorsement adds a few additional days. CDSCO retains discretion on timing.

Where Kisunla gets dispensed in India

A focused group of India institutions handle named-patient imports of high-acuity specialty products as established workflow, with the in-house clinical, pharmacy, and (where relevant) cell-therapy laboratory infrastructure and neurologists and memory-disorders specialists experienced with both the clinical management and the CDSCO application set. Biomarker-confirmed amyloid pathology (amyloid PET or CSF Abeta42/40 and phospho-tau), APOE genotyping (with informed consent and a clear plan for ARIA risk stratification), baseline brain MRI within the prior 12 months, monthly IV infusion logistics, an MRI surveillance schedule (typically before infusions 2, 3, 4, and 7), serial amyloid PET imaging at 6-month and 12-month intervals to assess plaque clearance and trigger discontinuation, anti-coagulant and antiplatelet co-prescription review, and a multidisciplinary plan for ARIA detection and management are the operational pillars of a Kisunla case.

Tertiary and major private hospitals that have demonstrated the capability for Kisunla-class therapy in India include All India Institute of Medical Sciences (AIIMS Delhi) neurology and cognitive disorders, National Institute of Mental Health and Neurosciences (NIMHANS Bangalore), Christian Medical College Vellore neurology, Apollo Hospitals memory and neurology services, Fortis Memorial Research Institute (Gurugram), Medanta The Medicity neurology, Kokilaben Dhirubhai Ambani Hospital (Mumbai) memory clinic, and Manipal Hospitals network neurology departments.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a licensed pharmaceutical establishment or a tertiary referral hospital that holds the necessary CDSCO relationship and files the application on the prescribing physician's behalf. The medicine then moves into the treating hospital's pharmacy under documented chain-of-custody.

Real cost picture for Kisunla in India

US WAC for Kisunla is approximately USD 32,500 per year for the standard monthly IV dosing in an adult of average weight, with annualised total cost of care (including biomarker workup, MRI surveillance, infusion centre fees, amyloid PET imaging for discontinuation assessment, and pre-infusion clinical visits) often USD 42,000 to USD 75,000 in the United States. The label-permitted discontinuation feature means many patients receive Kisunla for 12 to 18 months rather than indefinitely.. The INR/USD conversion (INR floats; reference rate approximately 83 INR per USD as of early 2026) means the annual US WAC for Kisunla translates to roughly INR 27 lakh per year at reference INR rates, with total cost of care often INR 35 to 62 lakh at reference rates. These figures are US WAC reference points only; manufacturer pricing on cross-border named-patient supply may differ from US WAC, and Reserve Meds' firm quote on a specific case reflects negotiated supply pricing rather than US list.

International logistics for a cold-chain biologic shipment to India typically runs USD 600 to USD 2,200 (approximately INR 50,000 to INR 180,000) depending on destination city, urgency, and pack size. CDSCO and customs fees on personal-import medicines are generally nominal on physician-attested medical necessity; cell and gene therapy shipments require additional CITES/quarantine clearance for cryogenic dewars. For Kisunla specifically, Kisunla is a refrigerated (2 to 8 degrees Celsius) monoclonal antibody supplied in single-dose vials. Validated thermal packaging with continuous temperature logging is the operational standard for the cross-border shipping leg. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, Indian health insurers assess named-patient imports case by case. The Insurance Regulatory and Development Authority of India (IRDAI) has not mandated coverage of cross-border imported medicines, and most policies exclude or sub-limit specialty biologics and cellular therapies. Corporate group policies and high-net-worth retail policies sometimes cover named-patient imports under exception requests. The Pradhan Mantri Jan Arogya Yojana and CGHS schemes do not extend to imported originator biologics. We do not promise coverage from any insurer; we supply the documentation set that lets your insurer assess the case.

Typical timeline for Kisunla in India

CDSCO routine processing for a Kisunla application from a complete submission typically tracks the regulator's standard window. For Kisunla specifically, the manufacturing or sourcing pathway adds an additional dimension beyond the regulator timeline. Drug sourcing through a DSCSA-compliant specialty distributor, validated cold-chain packaging, and customs clearance scheduled to avoid extreme temperature exposure are the operational steps that translate a regulatory approval into a delivered dose. End-to-end, most adult cases complete within 4 to 8 weeks from first complete documentation, depending on regulator queue and shipping lane.

We do not promise specific case timelines. Central Drugs Standard Control Organisation (CDSCO) retains discretion on application review, manufacturers retain discretion on slot allocation and supply, and shipping lanes are subject to customs and weather. The figures above describe typical experience at experienced centres, not contractual commitments.

What your physician needs to provide

For a India-licensed neurologist or memory-disorders specialist prescribing Kisunla through the CDSCO pathway, the clinical justification letter is the cornerstone of the application. For Kisunla, the clinical justification letter typically documents the patient's clinical diagnosis (mild cognitive impairment due to AD or mild Alzheimer's dementia per NIA-AA criteria), the biomarker confirmation method (amyloid PET imaging or CSF Abeta42/40 ratio and phospho-tau181), baseline cognitive testing (MMSE, MoCA, or CDR Sum of Boxes), the APOE genotype with informed consent for testing, the baseline brain MRI report within the prior 12 months (assessing pre-existing microhaemorrhages, superficial siderosis, and other ARIA-relevant findings), the planned MRI surveillance schedule, and the planned amyloid PET imaging schedule for discontinuation assessment. The letter also documents any anticoagulant or antiplatelet therapy and the prescriber's plan for managing this in the context of ARIA risk.

The physician's State Medical Council registration number and treating hospital CDSCO/state drug controller registration, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. Reserve Meds supplies a template clinical justification letter populated with the FDA-label criteria, the prior-therapy framing, and the chain-of-custody specifics; the treating physician edits to the patient's actual case and signs.

Common questions about Kisunla in India

Will my India insurer cover this? On the insurance side, Indian health insurers assess named-patient imports case by case. The Insurance Regulatory and Development Authority of India (IRDAI) has not mandated coverage of cross-border imported medicines, and most policies exclude or sub-limit specialty biologics and cellular therapies. Corporate group policies and high-net-worth retail policies sometimes cover named-patient imports under exception requests. The Pradhan Mantri Jan Arogya Yojana and CGHS schemes do not extend to imported originator biologics. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital. We do not promise coverage from any insurer.

How is Kisunla different from Leqembi? Both are FDA-approved anti-amyloid monoclonal antibodies for early Alzheimer's disease. Kisunla targets pyroglutamate-modified amyloid beta deposited as plaque, dosed monthly IV. Leqembi targets soluble protofibrils and insoluble fibrils, dosed biweekly IV. Kisunla's distinguishing feature is the FDA-label provision for discontinuation once amyloid plaque clearance is confirmed by amyloid PET, which typically occurs within 6 to 18 months in approximately half of treated patients. Leqembi is given indefinitely under standard practice. Choice depends on the neurologist's judgment, the patient's logistical situation, and the comparative ARIA profile.

Do I need an amyloid PET scan before starting Kisunla? Yes, or alternatively a CSF biomarker confirming amyloid pathology. Beyond the initial diagnostic scan, Kisunla treatment also involves serial amyloid PET imaging at approximately 6-month and 12-month intervals to assess plaque clearance and trigger discontinuation under the FDA-label provision.

What is ARIA and what is the risk with Kisunla? Amyloid-related imaging abnormalities (ARIA) are MRI-detected findings of brain oedema (ARIA-E) or haemorrhages/microhaemorrhages (ARIA-H) that occur as a class effect of anti-amyloid antibody therapy. In the TRAILBLAZER-ALZ 2 pivotal trial, radiographic ARIA-E occurred in approximately 24 percent of Kisunla-treated patients, with symptomatic ARIA-E in approximately 6 percent. APOE epsilon-4 homozygotes carry substantially higher risk than non-carriers. Most ARIA resolves with temporary or permanent treatment discontinuation.

Why can Kisunla be stopped after amyloid clearance? The mechanism of Kisunla, which targets deposited amyloid plaque, lends itself to a finite treatment course: once amyloid plaque is cleared, continued antibody dosing has no further plaque to clear. The TRAILBLAZER-ALZ 2 trial design included an amyloid-PET-triggered discontinuation arm, and the FDA label permits clinicians to discontinue therapy once plaque clearance is confirmed. This is operationally and economically distinctive within the anti-amyloid class.

How is APOE genotype used in Kisunla decisions? The Kisunla label includes APOE genotype information to inform shared decision-making about ARIA risk. APOE epsilon-4 homozygotes face the highest ARIA risk and require the most intensive MRI surveillance. Some neurologists adjust the threshold for initiating treatment or use a different surveillance cadence. Genotyping is performed once, prior to initiation, with informed consent that addresses the implications for the patient and biological relatives.

Will Kisunla reverse my mother's Alzheimer's disease? No. Kisunla slows the rate of cognitive and functional decline; it does not reverse existing cognitive impairment. In the TRAILBLAZER-ALZ 2 trial, treatment slowed the rate of decline on the integrated AD Rating Scale by approximately 22 to 35 percent over 18 months versus placebo, with the larger effect in the low-tau subgroup. Families consider this benefit alongside the ARIA risk and the infusion logistics.

Can Kisunla be combined with donepezil or memantine? Yes. Combination with cholinesterase inhibitors and memantine is permitted and common; the mechanisms are distinct and complementary.

What about competing products in this class? Within the anti-amyloid antibody class, Leqembi (lecanemab, Eisai / Biogen) is the principal alternative, with a different binding target (soluble protofibrils plus insoluble fibrils) and a biweekly IV dosing schedule. Aducanumab (Aduhelm, Biogen) was effectively withdrawn from the US market in early 2024. Symptomatic therapy with cholinesterase inhibitors (donepezil, rivastigmine, galantamine) and the NMDA antagonist memantine remains standard of care alongside or following anti-amyloid therapy. Reserve Meds coordinates whichever specific product the treating physician has prescribed.

Where Reserve Meds fits in Kisunla cases

Reserve Meds is a US-based concierge coordinator. We do not replace your neurologist or memory-disorders specialist, we do not replace the Central Drugs Standard Control Organisation (CDSCO), and we do not replace your dispensing pharmacy or treating hospital. For Kisunla specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated cold-chain or cryogenic logistics with continuous temperature logging into India, and assign a single named coordinator through the case.

For anti-amyloid antibody cases, our coordinator role spans the biomarker-workup, infusion-cadence, and MRI-surveillance arc rather than a single dispensing event: amyloid biomarker scheduling support, recurring shipments aligned to the dosing schedule, MRI cadence reminders, and ARIA reporting workflow with the treating neurologist or memory-disorders specialist. No prior Reserve Meds case experience for Kisunla is logged yet; standard NPP coordination under our neurology biologic playbook applies.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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